

TDMS No. 20310 - 04

Test Type: 26-39 WEEKS

Route: GAVAGE

Species/Strain: MICE/C3B6F1-+/Trp53(tm1Brd)

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

AZT+3TC combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 05/04/2010

Time Report Requested: 12:30:59

First Dose M/F: NA / 12/22/06

Lab: NCTR

C Number: C20310B

Lock Date: 04/20/2010

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Female

TDMSE Version: 2.2.0

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P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

AZT+3TC combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 05/04/2010

Time Report Requested: 12:30:59

First Dose M/F: NA / 12/22/06

Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Disposition Summary						
Animals Initially In Study	25	25	25	25	24	25
Early Deaths						
Moribund Sacrifice		1		1	2	1
Natural Death				1	1	
Survivors						
Moribund Sacrifice		2	3	1	2	1
Natural Death		2	2	2		1
Terminal Sacrifice	25	20	20	20	19	22
Animals Examined Microscopically	25	25	25	25	24	25

ALIMENTARY SYSTEM

Gallbladder	(25)	(23)	(23)	(22)	(23)	(23)
Intestine Large, Cecum	(25)	(23)	(23)	(22)	(23)	(24)
Hyperplasia, Lymphoid			1 (4%)			
Intestine Small, Duodenum	(25)	(23)	(23)	(22)	(23)	(24)
Intestine Small, Ileum	(25)	(23)	(23)	(22)	(23)	(24)
Liver	(25)	(25)	(23)	(24)	(23)	(25)
Basophilic Focus		1 (4%)				
Clear Cell Focus			1 (4%)			
Hematopoietic Cell Proliferation		1 (4%)		1 (4%)		
Hepatodiaphragmatic Nodule			1 (4%)			
Infiltration Cellular, Lymphocyte	1 (4%)	3 (12%)	2 (9%)	6 (25%)	3 (13%)	2 (8%)
Inflammation, Chronic Active	1 (4%)	2 (8%)	1 (4%)	2 (8%)	2 (9%)	1 (4%)
Necrosis						1 (4%)
Tension Lipidosis	2 (8%)		2 (9%)	3 (13%)	2 (9%)	
Vacuolization Cytoplasmic	14 (56%)	13 (52%)	14 (61%)	11 (46%)	13 (57%)	17 (68%)
Centrilobular, Degeneration				1 (4%)		
Mesentery	(0)	(1)	(0)	(0)	(0)	(0)
Fat, Necrosis						
Pancreas	(25)	(25)	(25)	(22)	(23)	(25)
Infiltration Cellular, Lymphocyte	2 (8%)	4 (16%)	2 (8%)	1 (5%)	3 (13%)	3 (12%)
Necrosis	1 (4%)					
Salivary Glands	(25)	(25)	(25)	(24)	(23)	(25)

a - Number of animals examined microscopically at site and number of animals with lesion

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First Dose M/F: NA / 12/22/06

Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Infiltration Cellular, Lymphocyte Stomach, Forestomach	22 (88%) (25)	17 (68%) (24)	18 (72%) (24)	19 (79%) (24)	16 (70%) (23)	18 (72%) (25)
Inflammation, Suppurative Inflammation, Chronic Active		1 (4%)			1 (4%)	
Ulcer	1 (4%)	1 (4%)			1 (4%)	
Epithelium, Hyperplasia	2 (8%)	1 (4%)			1 (4%)	
Stomach, Glandular	(25)	(23)	(23)	(22)	(23)	(25)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(25)	(25)	(25)	(25)	(23)	(25)
Heart	(25)	(25)	(25)	(25)	(24)	(25)
Inflammation, Chronic Active			1 (4%)			
Mineralization			1 (4%)	1 (4%)		
ENDOCRINE SYSTEM						
Adrenal Cortex	(25)	(24)	(24)	(25)	(23)	(25)
Accessory Adrenal Cortical Nodule	1 (4%)			1 (4%)		
Hypertrophy	1 (4%)					
Infiltration Cellular, Polymorphonuclear						
Vacuolization Cytoplasmic	16 (64%)	14 (58%)	16 (67%)	16 (64%)	13 (57%)	15 (60%)
Subcapsular, Hyperplasia	25 (100%)	24 (100%)	24 (100%)	24 (96%)	22 (96%)	24 (96%)
Islets, Pancreatic	(25)	(24)	(25)	(25)	(23)	(25)
Hyperplasia		2 (8%)		1 (4%)		1 (4%)
Parathyroid Gland	(20)	(23)	(21)	(20)	(18)	(21)
Cyst						1 (5%)
Infiltration Cellular, Lymphocyte					1 (6%)	
Pituitary Gland	(25)	(25)	(24)	(25)	(23)	(24)
Fibrosis			1 (4%)			
Pars Distalis, Hyperplasia						
Thyroid Gland	(23)	(24)	(25)	(23)	(22)	(25)
Cyst				1 (4%)		
Ectopic Thymus	3 (13%)		1 (4%)		1 (5%)	1 (4%)

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First Dose M/F: NA / 12/22/06

Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
GENERAL BODY SYSTEM						
Tissue NOS	(0)	(0)	(0)	(1)	(0)	(0)
GENITAL SYSTEM						
Clitoral Gland	(24)	(24)	(23)	(21)	(21)	(24)
Acinus, Degeneration	9 (38%)	12 (50%)	6 (26%)	5 (24%)	6 (29%)	6 (25%)
Duct, Ectasia						
Ovary	(25)	(24)	(25)	(24)	(23)	(25)
Atrophy	1 (4%)	1 (4%)	1 (4%)			
Cyst	1 (4%)	3 (13%)	1 (4%)	2 (8%)	3 (13%)	3 (12%)
Cyst Dermoid			1 (4%)			
Hemorrhage						
Uterus	(25)	(25)	(25)	(23)	(23)	(25)
Atrophy			1 (4%)			
Degeneration, Cystic		1 (4%)				
Endometrium, Hyperplasia, Cystic	22 (88%)	19 (76%)	19 (76%)	19 (83%)	17 (74%)	18 (72%)
Vagina	(25)	(24)	(24)	(24)	(23)	(25)
Infiltration Cellular, Polymorphonuclear		2 (8%)		2 (8%)		1 (4%)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(25)	(24)	(24)	(23)	(23)	(25)
Fibrosis			1 (4%)			
Hyperplasia	1 (4%)	2 (8%)	2 (8%)	1 (4%)	3 (13%)	
Lymph Node	(1)	(3)	(1)	(3)	(4)	(3)
Lumbar, Hyperplasia, Lymphoid						1 (33%)
Lumbar, Sinus, Dilatation		1 (33%)				
Pancreatic, Hyperplasia, Lymphoid						1 (33%)
Renal, Angiectasis		1 (33%)				
Renal, Hyperplasia, Lymphoid						1 (33%)
Renal, Thrombus		1 (33%)				

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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Lymph Node, Mandibular	(25)	(25)	(24)	(24)	(23)	(25)
Hyperplasia, Lymphoid	3 (12%)		3 (13%)	4 (17%)	2 (9%)	4 (16%)
Lymph Node, Mesenteric	(25)	(24)	(23)	(24)	(23)	(25)
Angiectasis		1 (4%)				
Hyperplasia, Lymphoid	1 (4%)	3 (13%)	3 (13%)	4 (17%)	3 (13%)	3 (12%)
Spleen	(25)	(25)	(24)	(24)	(23)	(25)
Hematopoietic Cell Proliferation	2 (8%)	8 (32%)	7 (29%)	6 (25%)	6 (26%)	2 (8%)
Hyperplasia, Lymphoid	20 (80%)	16 (64%)	17 (71%)	14 (58%)	14 (61%)	19 (76%)
Thymus	(25)	(21)	(22)	(22)	(24)	(25)
Atrophy	1 (4%)		2 (9%)			
Hyperplasia, Lymphoid	6 (24%)	2 (10%)	2 (9%)	8 (36%)	6 (25%)	9 (36%)

INTEGUMENTARY SYSTEM

Mammary Gland	(25)	(25)	(25)	(23)	(23)	(25)
Skin	(25)	(25)	(25)	(25)	(23)	(25)
Inflammation, Suppurative		1 (4%)				
Ulcer		1 (4%)				

MUSCULOSKELETAL SYSTEM

Bone	(0)	(0)	(2)	(0)	(0)	(2)
Bone, Femur	(25)	(25)	(25)	(25)	(24)	(25)
Fibro-Osseous Lesion	1 (4%)					
Skeletal Muscle	(0)	(1)	(2)	(0)	(0)	(0)
Degeneration			1 (50%)			

NERVOUS SYSTEM

Brain, Brain Stem	(25)	(24)	(25)	(24)	(23)	(25)
Brain, Cerebellum	(25)	(24)	(25)	(24)	(23)	(25)
Hemorrhage		1 (4%)				
Brain, Cerebrum	(25)	(24)	(25)	(24)	(23)	(25)
Mineralization	2 (8%)			3 (13%)		1 (4%)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
Peripheral Nerve Axon, Degeneration	(0)	(0)	(1) 1 (100%)	(0)	(0)	(0)
RESPIRATORY SYSTEM						
Lung	(25)	(24)	(24)	(24)	(24)	(25)
Hemorrhage				1 (4%)		1 (4%)
Infiltration Cellular, Lymphocyte		1 (4%)				1 (4%)
Inflammation, Chronic Active					1 (4%)	
Metaplasia, Osseous		1 (4%)				1 (4%)
Nose	(25)	(25)	(25)	(24)	(24)	(25)
Hyaline Droplet	1 (4%)	3 (12%)	4 (16%)	1 (4%)	6 (25%)	4 (16%)
Trachea	(25)	(24)	(24)	(24)	(23)	(25)
SPECIAL SENSES SYSTEM						
Eye	(25)	(23)	(23)	(22)	(23)	(24)
Cataract						
Harderian Gland	(25)	(24)	(25)	(25)	(23)	(25)
Infiltration Cellular, Lymphocyte	2 (8%)				1 (4%)	1 (4%)
Inflammation, Chronic Active			1 (4%)			
URINARY SYSTEM						
Kidney	(25)	(24)	(24)	(24)	(23)	(25)
Casts Protein	14 (56%)	14 (58%)	8 (33%)	10 (42%)	12 (52%)	15 (60%)
Hydronephrosis						
Infarct	1 (4%)					
Infiltration Cellular, Lymphocyte	11 (44%)	10 (42%)	11 (46%)	15 (63%)	11 (48%)	13 (52%)
Metaplasia, Osseous						
Mineralization			1 (4%)			
Renal Tubule, Regeneration			1 (4%)			
Urinary Bladder	(25)	(24)	(24)	(23)	(23)	(25)
Infiltration Cellular, Lymphocyte	8 (32%)	4 (17%)	8 (33%)	4 (17%)	8 (35%)	5 (20%)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle	AZT 60	3TC 37.5	NVP 10.5	AZT 60 3TC 37.5	A20,3T12.5,NV3.5
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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
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Disposition Summary

Animals Initially In Study	24	25
Early Deaths		
Moribund Sacrifice	1	
Natural Death	1	
Survivors		
Moribund Sacrifice	1	2
Natural Death		2
Terminal Sacrifice	21	21
Animals Examined Microscopically	22	25

ALIMENTARY SYSTEM

Gallbladder	(21)	(24)
Intestine Large, Cecum	(21)	(23)
Hyperplasia, Lymphoid		
Intestine Small, Duodenum	(21)	(24)
Intestine Small, Ileum	(21)	(23)
Liver	(22)	(25)
Basophilic Focus	1 (5%)	
Clear Cell Focus	1 (5%)	
Hematopoietic Cell Proliferation		
Hepatodiaphragmatic Nodule		
Infiltration Cellular, Lymphocyte	4 (18%)	4 (16%)
Inflammation, Chronic Active		3 (12%)
Necrosis		
Tension Lipidosis	4 (18%)	3 (12%)
Vacuolization Cytoplasmic	13 (59%)	15 (60%)
Centrilobular, Degeneration		3 (12%)
Mesentery	(0)	(2)
Fat, Necrosis		2 (100%)
Pancreas	(21)	(24)
Infiltration Cellular, Lymphocyte	5 (24%)	2 (8%)
Necrosis		
Salivary Glands	(22)	(25)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
Infiltration Cellular, Lymphocyte Stomach, Forestomach	12 (55%) (21)	20 (80%) (24)
Inflammation, Suppurative Inflammation, Chronic Active Ulcer		
Epithelium, Hyperplasia Stomach, Glandular	(21)	1 (4%) (23)
CARDIOVASCULAR SYSTEM		
Blood Vessel	(22)	(25)
Heart	(22)	(25)
Inflammation, Chronic Active Mineralization		
ENDOCRINE SYSTEM		
Adrenal Cortex	(22)	(25)
Accessory Adrenal Cortical Nodule Hypertrophy		
Infiltration Cellular, Polymorphonuclear		1 (4%)
Vacuolization Cytoplasmic	16 (73%)	18 (72%)
Subcapsular, Hyperplasia	20 (91%)	24 (96%)
Islets, Pancreatic	(22)	(25)
Hyperplasia		1 (4%)
Parathyroid Gland	(21)	(23)
Cyst		
Infiltration Cellular, Lymphocyte		
Pituitary Gland	(22)	(23)
Fibrosis		
Pars Distalis, Hyperplasia		1 (4%)
Thyroid Gland	(22)	(25)
Cyst	1 (5%)	
Ectopic Thymus	2 (9%)	2 (8%)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

GENERAL BODY SYSTEM

GENERAL BODY SYSTEM	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
Tissue NOS	(0)	(0)

GENITAL SYSTEM

Clitoral Gland	(22)	(22)
Acinus, Degeneration	5 (23%)	11 (50%)
Duct, Ectasia		1 (5%)
Ovary	(22)	(25)
Atrophy	1 (5%)	
Cyst	1 (5%)	
Cyst Dermoid		
Hemorrhage		1 (4%)
Uterus	(22)	(25)
Atrophy		
Degeneration, Cystic		
Endometrium, Hyperplasia, Cystic	16 (73%)	17 (68%)
Vagina	(22)	(23)
Infiltration Cellular, Polymorphonuclear		2 (9%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(22)	(24)
Fibrosis		
Hyperplasia		3 (13%)
Lymph Node	(1)	(4)
Lumbar, Hyperplasia, Lymphoid		
Lumbar, Sinus, Dilatation		
Pancreatic, Hyperplasia, Lymphoid		
Renal, Angiectasis		
Renal, Hyperplasia, Lymphoid		
Renal, Thrombus		

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE

AZT40,3TC25,NVP7

A60,3T37.5,N10.5

Lymph Node, Mandibular	(22)	(25)
Hyperplasia, Lymphoid	2 (9%)	1 (4%)
Lymph Node, Mesenteric	(21)	(24)
Angiectasis		
Hyperplasia, Lymphoid	2 (10%)	3 (13%)
Spleen	(22)	(25)
Hematopoietic Cell Proliferation	8 (36%)	7 (28%)
Hyperplasia, Lymphoid	16 (73%)	16 (64%)
Thymus	(21)	(24)
Atrophy		
Hyperplasia, Lymphoid	2 (10%)	5 (21%)

INTEGUMENTARY SYSTEM

Mammary Gland	(22)	(25)
Skin	(22)	(25)
Inflammation, Suppurative		
Ulcer		

MUSCULOSKELETAL SYSTEM

Bone	(1)	(0)
Bone, Femur	(22)	(25)
Fibro-Osseous Lesion		
Skeletal Muscle	(0)	(0)
Degeneration		

NERVOUS SYSTEM

Brain, Brain Stem	(21)	(25)
Brain, Cerebellum	(21)	(25)
Hemorrhage		
Brain, Cerebrum	(21)	(25)
Mineralization	2 (10%)	

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
Peripheral Nerve Axon, Degeneration	(0)	(0)
RESPIRATORY SYSTEM		
Lung	(22)	(25)
Hemorrhage		
Infiltration Cellular, Lymphocyte		3 (12%)
Inflammation, Chronic Active		
Metaplasia, Osseous		
Nose	(22)	(25)
Hyaline Droplet	1 (5%)	6 (24%)
Trachea	(21)	(25)
SPECIAL SENSES SYSTEM		
Eye	(21)	(23)
Cataract		1 (4%)
Harderian Gland	(22)	(24)
Infiltration Cellular, Lymphocyte		
Inflammation, Chronic Active		
URINARY SYSTEM		
Kidney	(22)	(25)
Casts Protein	9 (41%)	15 (60%)
Hydronephrosis		3 (12%)
Infarct		
Infiltration Cellular, Lymphocyte	7 (32%)	11 (44%)
Metaplasia, Osseous		1 (4%)
Mineralization		
Renal Tubule, Regeneration		
Urinary Bladder	(22)	(25)
Infiltration Cellular, Lymphocyte	5 (23%)	3 (12%)

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C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	AZT40,3TC25,NVP7	A60,3T37.5,N10.5
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*** END OF REPORT ***

a - Number of animals examined microscopically at site and number of animals with lesion